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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,765	08/24/2006	Greg P. Beer	47082-168USPX	2504

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EXAMINER	
SALZMAN, KOURTNEY R	

ART UNIT	PAPER NUMBER
1795	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,765	BEER ET AL.	
	Examiner	Art Unit	
	KOURTNEY R. SALZMAN	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 2, 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-36* is/are pending in the application.

4a) Of the above claim(s) *12-20 and 33-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-11 and 21-32* is/are rejected.

7)☒ Claim(s) *26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :January 26, 2007 and March 6, 2009.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 9-11 and 21-32, drawn to biosensor, classified in class 204, subclass 403.01.

II. Claims 12-20 and 33-36, drawn to method of use, classified in class 205, subclass 777.5.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product has separate utility as it can be used as a traditional biosensor for concentration reading with just one voltage application as opposed to the two required by the method group II.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with John Gatz on October 15, 2009 a provisional election was made without traverse to prosecute the invention of group I, claims 1-7, 9-11 and 21-32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-20 and 33-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

6. Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 26 is a duplicate of claim 25, therefore it fails to further limit the claim before it.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by HENNING et al (US 6,565,738).

Regarding claim 1, HENNING et al teaches a biosensor comprising a reagent layer with a mediator (ferricyanide), the reduced (or oxidizable) species (internal reference) ferrocyanide and enzyme (glutamate oxidase) in column 13, lines 48-53, reactions 2 and 3 and lines 15-20. The specification of the instant application discloses the internal reference can be a mediator species on page 3, line 24 of the instant application and this combination is taught on pages 15 and 16 of the specification as working in accordance with the present invention. Therefore, ferrocyanide can be interpreted to function as the internal reference.

Regarding claim 2, the example of ferrocyanide as the internal reference and ferricyanide as the mediator is described on pages 15 and 16 of the specification to redox at the desired potentials.

Regarding claim 7, HENNING et al teaches the working and counter electrodes (206 and 208 respectively of figure 2) to be present, as the reagent mixture is taught in column 13 to be applied to the working electrode.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 7, 21-22 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by HODGES et al (US PG PUB 2001/0052470).

Regarding claim 1, HODGES et al teaches a biosensor with reagent mixture comprising an enzyme (GOD), ferricyanide (mediator) and ferrocyanide (internal reference) in paragraph 9. The specification of the instant application discloses the internal reference can be a mediator species on page 3, line 24 of the instant application and this combination is taught on pages 15 and 16 of the specification as working in

accordance with the present invention. Therefore, ferrocyanide can be interpreted to function as the internal reference.

Regarding claim 2, the example of ferrocyanide as the internal reference and ferricyanide as the mediator is described on pages 15 and 16 of the specification to redox at the desired potentials.

Regarding claim 7, HODGES et al teaches the use of a counter and working electrode through the specification including paragraph 6.

Regarding claims 21, 30, 31 and 32, HODGES et al teaches a biosensor with reagent mixture comprising an enzyme (GOD), ferricyanide (mediator) and ferrocyanide (internal reference) in paragraph 9. The specification of the instant application discloses the internal reference can be a mediator species on page 3, line 24 of the instant application and this combination is taught on pages 15 and 16 of the specification as working in accordance with the present invention. Therefore, ferrocyanide can be interpreted to function as the internal reference. The chemical application or batch formation is discussed in paragraphs 69-70.

Regarding claim 22, the example of ferrocyanide as the internal reference and ferricyanide as the mediator is described on pages 15 and 16 of the specification to redox at the desired potentials.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over HENNING (US 6,565,738), in view of BLOCZYNSKI et al (US 5,520,786).

HENNING et al teaches all the limitations of claim 1, including the use of any known mediator for the reagent layer in column 13, lines 57-58.

Regarding claim 3, BLOCZYNSKI et al teaches the use of mediator 3-phenylimino-3H-phenothiazine in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (3-phenylimino-3H-phenothiazine, BLOCZYNSKI et al) for another known mediator (ferricyanide, HENNING et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction.

Regarding claim 4, HENNING et al teaches the ferrocyanide to be present as the internal reference.

Regarding claims 5 and 6, since the same materials are present as the internal reference and mediator, the biosensor would function just as required when electronics outside the sensor supply the two potentials to the sensor itself. For the purpose of this apparatus claim, the biosensor would be capable of reacting with the potentials as sufficiently required by the claim, as these are inherent reactions which the biosensor will perform when the process conditions specified are applied.

15. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over HENNING et al (US 6,565,738), in view of NAGAKAWA et al (US PG PUB 2004/0245121 A1).

HENNING et al teaches all the limitations of claim 1, including the use of any known mediator for the reagent layer in column 13, lines 57-58.

Regarding claim 9, NAGAKAWA et al teaches the use of a Ru complex mediator with substitutions, or ruthenium hexamine, as discussed in column 3, line 57- column 4, line 9.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (ruthenium hexamine, NAGAKAWA et al) for another known mediator (ferricyanide, HENNING et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction.

Regarding claim 10, HENNING et al teaches the ferrocyanide to be present as the internal reference.

Regarding claim 11, NAGAKAWA et al teaches the use of the mediator with glucose oxidase for glucose measurements in column 4, lines 19-29 but will also be effective with any oxidation-reduction enzyme, as in HENNING et al.

16. Claims 3-6 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over HODGES (US PG PUB 2001/0052470), in view of BLOCZYNSKI et al (US 5,520,786).

HODGES et al teaches all the limitations of claim 1 and 21.

Regarding claims 3 and 23, BLOCZYNSKI et al teaches the use of mediator 3-phenylimino-3H-phenothiazine in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (3-phenylimino-3H-phenothiazine, BLOCZYNSKI et al) for another known mediator (ferricyanide, HODGES et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction.

Regarding claim 4 and 24, HODGES et al teaches the ferrocyanide to be present as the internal reference, as discussed in the above rejection.

Regarding claims 5, 6, 25 and 26, since the same materials are present as the internal reference and mediator, the biosensor would function just as required when electronics outside the sensor supply the two potentials to the sensor itself. For the purpose of this apparatus claim, the biosensor would be capable of reacting with the potentials as sufficiently required by

the claim, as these are inherent reactions which the biosensor will perform when the process conditions specified are applied.

17. Claims 9-11 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over HODGES et al (US PG PUB 2001/0052470), in view of NAGAKAWA et al (US PG PUB 2004/0245121 A1).

HODGES et al teaches all the limitations of claims 1 and 21.

Regarding claims 9 and 27, NAGAKAWA et al teaches the use of a Ru complex mediator with substitutions, or ruthenium hexamine, as discussed in column 3, line 57- column 4, line 9.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (ruthenium hexamine, NAGAKAWA et al) for another known mediator (ferricyanide, HODGES et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction.

Regarding claims 10 and 28, HODGES et al teaches the ferrocyanide to be present as the internal reference, as discussed the above rejection.

Regarding claims 11 and 29, HODGES et al teaches the enzyme to be GOD or glucose oxidase in paragraph 9. Furthermore, NAGAKAWA et al teaches the use of the mediator with glucose oxidase for glucose

measurements in column 4, lines 19-29 but will also be effective with any oxidation-reduction enzyme, as in HODGES et al.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KOURTNEY R. SALZMAN whose telephone number is (571)270-5117. The examiner can normally be reached on Monday to Thursday 6:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

krs
12/4/2009